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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

PAK, YONG D

ART UNIT PAPER NUMBER

1652

DATE MAILED: 01/26/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Applicant(s)

10/031,547

Applicant(s)

PFALLER, RUPERT

Examiner

Yong D Pak

Art Unit

1652

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 August 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 8-16 is/are pending in the application.
- 4a) Of the above claim(s) 12-14 and 16 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 8-11 and 15 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 18 January 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>6/4/02</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This application is a 371 of PCT/EP00/06091.

The preliminary amendment filed on January 18, 2002, canceling claims 1-7 and adding claims 8-16, has been entered.

Claims 8-16 are pending. Claims 12-14 and 16 are withdrawn. Claims 8-11 and 15 are under consideration.

Election/Restrictions

Applicant's election with traverse of Group I in the reply filed on November 18, 2004 is acknowledged. The traversal is on the ground(s) that a search of Group I would include Groups II-III because the groups use a pyrF gene. This is not found persuasive because Group I is drawn to a pyrF gene and the encoded polypeptide while Group II is drawn to a method of making a fungal strain having an auxotrophic gene and Group III is drawn to an expression system comprising a pyrF gene which complements an auxotrophic gene defect. Therefore, the search of Group I is not co-extensive and an unduly extensive and burdensome search is required for Groups II-III that is not required for Group I. Applicants also argue that a compact prosecution would be promoted if a search were conducted for Groups I-II. This is not found persuasive because an unduly extensive and burdensome search would impede prosecution of the application. Applicants also argue that filing of multiple patent applications does not serve to promote public interest. This is not found persuasive because a reasonable and unburdensome search would better serve the public in issuing a valid patent.

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The requirement is still deemed proper and is therefore made FINAL.

Claims 12-14 and 16 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on November 18, 2004.

Priority

Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Information Disclosure Statement

The information disclosure statement (IDS) submitted on June 4, 2002 is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Claim Objections

Claim 8 is objected to because of the following informalities: the phrases "in a region" and "from position" appear to be redundant in the claim. Applicants are urged to remove one of the phrases. Appropriate correction is required.

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Claims 10-11 are objected to because of the following informalities: In claim 10, the article "a" in front of DNA sequence should be amended to recite "the DNA sequence as claimed in claim 8" to clearly refer back to its parent claim. In claim 11, the article "a" in front of "an expression vector" should be amended to recite "the expression vector as claimed in claim 10" to clearly refer back to its parent claim.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 8, 9 and 11 are rejected under 35 U.S.C. 101 because the claimed invention is directed to a non-statutory subject matter.

Claims 8-9, as written, does not sufficiently distinguish over nucleic acids or amino acids as they exist naturally because the claim does not particularly point out any non-naturally occurring differences between the claimed product and the naturally occurring product. Claim 11, as written, do not sufficiently distinguish over microorganisms as they exist naturally because the claims do not particularly point out any non-naturally occurring differences between the claimed products and the naturally occurring products, such as being "transformed" with the vector of claim 1 or being a "recombinant host cell". In the absence of the hand of man, the naturally occurring products are considered non-statutory subject matter. Claims 8, 9 and 11 should be amended to indicate the hand of the inventor, e.g., by insertion of "Isolated" or "Purified"

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or "transformed" as taught by the specification. See *Diamond v. Chakrabarty*, 447 U.S. 303, 206 USPQ 193 (1980). See MPEP 2105.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 15 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 15 recites the term "gene". The metes and bounds of the phrase in the context of the above claim is not clear to the Examiner. A gene comprises of a coding sequence and introns, exons and regulatory sequences. A perusal of the specification did not provide the Examiner with a specific definition for the above phrase. Therefore, it is not clear whether the above term in said claims encompass the intronic and regulatory sequences or is limited to a cDNA. Examiner suggests replacing the above term with "polynucleotide".

It is also unclear as to which "protein" & "gene" applicants are referring to because the microorganism of claim 11 would be capable of producing a large number of proteins when it is cultured.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

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The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 8-11 and 15 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a polynucleotide encoding pyrF of SEQ ID NO:3 and the polypeptide of SEQ ID NO:3, does not reasonably provide enablement for a polynucleotide having a sequence homology of at least 70% to SEQ ID NOs: 1 or 2 or a polypeptide having a sequence homology of at least 70% to SEQ ID NO:3. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Claims 8; 10-11 and 15 are drawn to a polynucleotide having a sequence homology of at least 70% to SEQ ID NOs: 1 or 2, wherein the polynucleotide encodes a polypeptide having pyrF activity, vector and microorganism comprising said polynucleotide and a method of producing said polypeptide. Claim 9 is drawn to a polypeptide having a sequence homology of at least 70% to SEQ ID NO:3, wherein the polypeptide has pyrF activity. Therefore, these claims are drawn to a genus of polypeptides having any structure.

The scope of the claims is not commensurate with the enablement provided by the disclosure with regard to the extremely large number of polynucleotides encoding pyrF and polypeptides having pyrF activity broadly encompassed by the claims. Since the amino acid sequence of a protein determines its structural and functional properties, predictability of which changes can be tolerated in a protein's amino acid sequence and

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obtain the desired activity requires a knowledge of and guidance with regard to which amino acids in the protein's sequence, if any, are tolerant of modification and which are conserved (i.e. expectedly intolerant to modification), and detailed knowledge of the ways in which the proteins' structure relates to its function. However, in this case the disclosure is limited to the nucleotide and encoded amino acid sequence of only one pyrF. It would require undue experimentation of the skilled artisan to make and use the claimed polynucleotides and polypeptides. The specification is limited to teaching the use of SEQ ID NO: 3 as a pyrF and SEQ ID NOs: 1 and 2 as polynucleotides encoding a pyrF but provides no guidance with regard to the making of variants and mutants or with regard to other uses. In view of the great breadth of the claim, amount of experimentation required to make the claimed polynucleotides and polypeptides, the lack of guidance, working examples, and unpredictability of the art in predicting function from a polypeptide primary structure, the claimed invention would require undue experimentation. As such, the specification fails to teach one of ordinary skill how to use the full scope of the polynucleotides and polypeptides encompassed by the claims.

While enzyme isolation techniques, recombinant and mutagenesis techniques are known, and it is routine in the art to screen for multiple substitutions or multiple modifications as encompassed by the instant claims, the specific amino acid positions within a protein's sequence where amino acid modifications can be made with a reasonable expectation of success in obtaining the desired activity/utility are limited in any protein and the result of such modifications is unpredictable. In addition, one skilled

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in the art would expect any tolerance to modification for a given protein to diminish with each further and additional modification, e.g. multiple substitutions.

The specification does not support the broad scope of the claims which encompass all modifications and fragments and variants of any polynucleotides having a sequence homology of at least 70% to SEQ ID NOs: 1 or 2 and any pyrF having a sequence homology of at least 70% to the enzyme SEQ ID NO:3 because the specification does not establish: (A) regions of the protein or encoded protein structure which may be modified without affecting pyrF activity; (B) the general tolerance of pyrF to modification and extent of such tolerance; (C) a rational and predictable scheme for modifying any amino acid residue with an expectation of obtaining the desired biological function (modification of up to 30% of the pyrF structure); and (D) the specification provides insufficient guidance as to which of the essentially infinite possible choices is likely to be successful.

Also, claim 15 is drawn to the production of the pyrF protein of SEQ ID NO:3 and and any polypeptides also expressed in the host cell system. The specification is enabled for a method of making the pyrF protein of SEQ ID NO:3 but not any or all proteins that the host microorganism of claim 11 produces because applicants have not taught what properties and activity any or all proteins have and how to use them. The specification is limited to a teaching of host cells that can be especially used to make the polypeptide encoded by SEQ ID NOs: 1 or 2.

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Thus, applicants have not provided sufficient guidance to enable one of ordinary skill in the art to make and use the claimed invention in a manner reasonably correlated with the scope of the claims broadly including pyrF and polynucleotides encoding pyrF with an enormous number of amino acid modifications of the catalases of SEQ ID NO:3 or the polynucleotides of SEQ ID NOs: 1 or 2. The scope of the claims must bear a reasonable correlation with the scope of enablement (*In re Fisher*, 166 USPQ 19 24 (CCPA 1970)). Without sufficient guidance, determination of pyrF genes and pyrF protein having the desired biological characteristics is unpredictable and the experimentation left to those skilled in the art is unnecessarily, and improperly, extensive and undue. See *In re Wands* 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988).

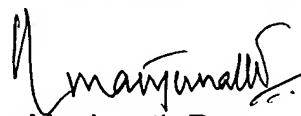
None of the claims are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yong Pak whose telephone number is 571-272-0935. The examiner can normally be reached 6:30 A.M. to 5:00 P.M. Monday through Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy can be reached on 571-272-0928. The fax phone numbers for the organization where this application or proceeding is assigned are 571-273-8300 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 571-272-1600.

Yong D. Pak
Patent Examiner 1652


Manjunath Rao
Primary Examiner 1652